

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

UNITED STATES OF AMERICA,

Plaintiff,

v.

CR-06-1362 JC

MARK E. VAN WORMER,

Defendant.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on Defendant's *Fifth Motion and Memorandum to Dismiss--Count 13 Felony Misbranding*, filed March 6, 2007 (*Doc. 36*). The issue before me on this Motion is whether the filing of the Indictment in this matter violated Defendant's rights under the Fifth Amendment to the United States Constitution such that dismissal of the Indictment is warranted. Having considered the parties' submissions, the relevant law, and having held a hearing on this Motion on April 19, 2007, I find the requested relief unwarranted. Accordingly, the Motion is denied.

I. Background

The Superseding Indictment in this matter charges Defendant Mark E. Van Wormer with frauds and swindles, alleging that Defendant, a physician, injected his patients with a substance not approved by the Federal Drug Administration (FDA), in violation of 18 U.S.C. § 1341 (Counts 1-12); misbranding a drug while held for sale, in that Defendant offered TRI-toxin for sale under the name of Botox® and Botox after the unapproved TRI-toxin was shipped in interstate commerce, in violation of 21 U.S.C. §§ 331(k) and 352(i)(3) (Count 13); and

tampering with documents, namely the files of the patients he injected with the TRI-toxin, in violation of 18 U.S.C. § 1512(c)(1) (Count 14).

These charges arise out of an investigation by FDA Miami Field Officers into the activities of Chad Livdahl, M.D., owner of a company called Toxin Research International, Inc. (TRI). TRI was distributing an unapproved drug derived from Botulinum Toxin Type A (“TRI-toxin”) to certain physicians across the country, labeling the drug “For Research Purposes Only” and “Not For Human Use,” but representing otherwise to the purchasers. *See* Mot., Ex. 8. Chad Livdahl was convicted of conspiracy to commit mail fraud, wire fraud, and misbranding, and one count of mail fraud. *See* Mot., Ex. 7, *United States v. Livdahl*, case No. 05-60021-CR-COHN.

While conducting a search of TRI’s offices in Arizona, FDA agents learned the names of physicians who had purchased the TRI-toxin. *Id.* The Defendant’s name was among them and the FDA, accordingly, began an investigation into Defendant’s conduct related to his purchases of TRI-toxin.

In the present Motion, Defendant seeks dismissal of Count 13 of the Superseding Indictment, charging him with felony misbranding and aiding and abetting in violation of 21 U.S.C. §§ 331(k), 333(a)(92), 352(1)(3) and 18 U.S.C. § 2. In support, Defendant argues that the statute and regulations require that he be provided with notice and opportunity to be heard on the misbranding charge, which he was not, prior to a recommendation for criminal prosecution.

II. Legal Standard

The question for the Court on a motion to dismiss an indictment is not whether the government has presented sufficient evidence to support the charge, but solely whether the allegations in the indictment, if true, are sufficient to establish a violation of the charged offense.

For the most part, that question does not involve any examination of the evidence.” *United States v. Todd*, 446 F.3d 1062, 1068 (10th Cir. 2006)(citing *United States v. Sampson*, 371 U.S. 75 (1962)).

III. Discussion

As a preliminary matter, Defendant initially asserts that he was denied due process under the Fourteenth Amendment, though in his Reply brief he acknowledges that the Fifth Amendment applies to actions of the federal government. The Court will consider the Motion under the Fifth Amendment.

Defendant claims that the FDA failed to provide him with notice and opportunity to be heard prior to recommending to the United States Attorney’s Office that he be prosecuted. Defendant identifies this right to notice and hearing in the statutory language of 21 U.S.C. § 335, which states in pertinent part, “United States Attorney for institution of a criminal proceeding, the person against whom such a proceeding is contemplated shall be given appropriate notice and opportunity to present his views.” Further, Defendant argues, the regulations promulgated pursuant to the Food, Drug and Cosmetic Act mandate that when “a person against whom criminal prosecution under the Federal Food, Drug and Cosmetic Act is contemplated...shall be given appropriate notice and opportunity to present information and views.” 21 C.F.R. § 7.84(a). Defendant asserts that he was not provided with a hearing, as required, prior to the FDA recommending that he be indicted.

It is both undisputed and well-settled that the hearing required by 21 U.S.C. § 335 is not a jurisdictional prerequisite to prosecution, *United States v. Dotterweich*, 320 U.S. 277, 279 (1943). Accordingly, Defendant does not argue against settled law, but instead asserts that his due process rights were violated based upon the administrative failure on the part of the FDA to

provide a pre-indictment hearing. In the hearing on this Motion, Defendant urged the Court to consider the arguments Defendant might have presented in such a hearing, focusing on mitigating circumstances which he believes might warrant some action short of criminal indictment.

The government contends that Defendant was not entitled to a hearing based upon the provisions of the regulations because the FDA referred the case to the United States Attorney for additional investigation. The government further argues that there can be no due process violation regardless, for Defendant will ultimately have opportunity to be heard at trial.

Because the hearing is not a jurisdictional prerequisite to prosecution, *U.S. v. Dotterweich*, 320 U.S. at 279, and the Defendant will have a full opportunity to be heard at trial, I find, as other courts have, that dismissal of the indictment is unprecedented and unwarranted. *See, e.g., United States v. Prigmore*, 243 F.3d 1 at 23 (1st Cir. 2001)(citing *Dotterweich* and stating, “even assuming that [defendants] were entitled to such notice and opportunity, the Supreme Court has made it clear that they are not entitled to dismissal of the prosecution.”). Accordingly, the Motion is denied.

Wherefore,

IT IS ORDERED that Defendant’s *Fifth Motion and Memorandum to Dismiss--Count 13 Felony Misbranding*, filed March 6, 2007 (*Doc. 36*), is DENIED.

Dated April 26, 2007.

s/John Edwards Conway

SENIOR UNITED STATES DISTRICT JUDGE

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